IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DEBRA COMPTON, Plaintiff, ***v.*** **AMERICAN MEDICAL SYSTEMS, INC.,** Defendant.	**C.A. No. _____** **JURY TRIAL DEMANDED**

FIRST COMPLAINT

Plaintiff, DEBRA COMPTON, by and through her attorneys, NAPOLI SHKOLNIK LLC, complaining of the defendant, respectfully allege upon information and belief, as follows:

PARTIES

1. At all times relevant herein, Plaintiff DEBRA COMPTON hereinafter "Plaintiff" or "Mrs. Compton"), is resident citizen of Wasilla, State of Alaska.

2. American Medical Systems, Inc. ("AMS") is a wholly owned subsidiary of defendant American Medical Systems Holdings Inc., Defendant AMS is a wholly owned subsidiary of defendant Endo Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings Inc. and Endo Health Solutions Inc. and is a Delaware corporation and may be served pursuant to 10 Del. C. § 3111 by serving its registered agent, Corporation Trust Company, at 1209 North Orange Street, Wilmington, Delaware 19801. AMS is a producer, manufacturer, and designer of transvaginal mesh product, including the AMS Monarc Subfascial Hammock, which is at issue here.

3. AMS shall be referred to hereinafter as "Defendant."

4. At all times material to this action, Defendant has designed, patented, manufactured, labeled, marketed, and sold and distributed a line of pelvic mesh products, including

the Monarc Subfascial Hammock. These products were designed primarily for the purposes of treating stress urinary incontinence and pelvic organ prolapse. These products share common design elements and common defects. Moreover, each of these products was cleared for sale in the U.S. after the Defendant made assertions to the Food and Drug Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety or efficacy.

5. The AMS defendant has conducted business and derived substantial revenue from New York.

6. AMS designed, manufactured, packaged, labeled, marketed, sold, and distributed the AMS Monarc Subfascial Hammock, including that which was implanted in Plaintiff as indicated in the paragraphs that follow.

7. The AMS defendant expected or should have expected its acts to have consequences within the State of Alaska, and derived substantial revenue from interstate commerce.

JURISDICTION

8. This Court has personal jurisdiction over the Defendant based on Diversity of Citizenship pursuant to 28 U.S.C. Section 1332(a)(1), and the amount in controversy is well in excess of the jurisdictional limit of $75,000.

FACTUAL BACKGROUND

A. Plaintiff Specific Allegations

9. Plaintiff DEBRA COMPTON was implanted with the AMS Monarc Subfascial Hammock sling pelvic mesh product on January 24, 2008, at Joint Base Elmendorf-Richardson Hospital in Elmendorf AFB, AK. Dr. Jeffery A. Simerville was the implanting surgeon.

10. At the time of implant, Plaintiff was suffering from cystocele and stress urinary incompetence.

11. Initially, the Monarc Sling resolved some of these issues. But Plaintiff began to suffer incontinence and chronic pain again after her surgery. Plaintiff suffered with these symptoms until approximately December 2020, when the chronic pain became too much to bear. On physical examination, Dr. Una Lee, Plaintiff's revision surgeon, noted that Plaintiff had transobturator mesh sling eroded into the lumen of the urethra, urinary obstruction, anterior vaginal wall mesh eroded into the vagina, dyspareunia, recurrent UTI'S, urinary incontinence, and pelvic pain.

12. Dr. Lee conducted a revision surgery on Plaintiff on December 7, 2020, wherein the Monarc sling was explanted from Plaintiff. It is not known for certain if all of the subject Monarc sling was removed at the time of the December 7. 2020 surgery.

13. However, Plaintiff DEBRA COMPTON continues to suffer from sudden and frequent urges, incontinence requiring use of pads, chronic pain in the pelvic area, pain with intercourse, pain with housework, cramping, and dyspareunia.

B. Background on AMS' Pelvic Mesh Products

14. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

15. Generally speaking, Defendant's varying Pelvic Mesh Products, including the Monarc sling, contain monofilament polypropylene mesh and/or collagen. Despite claims that polypropylene is inert, the scientific evidence shows that this material is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population

implanted with Defendant's Pelvic Mesh Products. This negative response promotes inflammation of the pelvic tissue and can contribute to the development of severe adverse reactions to the mesh. Furthermore, Defendant's collagen products cause hyper-inflammatory responses leading to problems including chronic pain and fibrotic reaction. Defendant's collagen products disintegrate after implantation in the female pelvis. The collagen products cause adverse tissue reactions, and are causally related to infection, as the collagen is a foreign material derived from animal tissue. Animal collagen is harsh upon the female pelvic tissue. It hardens in the body. When mesh is inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

16. Defendant sought and obtained FDA clearance to market the Monarc Sling (and its other pelvic mesh products) under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to the Products.

17. On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 reports of complications (otherwise known as "adverse events") that had been reported over a three-year period relating to pelvic mesh products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that the Defendant is one of the manufacturers of the products that are the subject of the notification. In 2008, the FDA described the complications associated with pelvic mesh products as "**rare**."

18. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**" (emphasis in the original).

19. The FDA Safety Communication also stated, "*Mesh contraction* (shrinkage) is a *previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA . . . Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (emphasis in original).

20. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks.

21. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

22. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper"). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

23. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginal

placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk." (Emphasis in original).

24. The FDA White Paper further stated that "these products are associated with serious adverse events . . . Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair."

25. In its White Paper, the FDA advises doctors to, *inter alia*, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications."

26. The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

27. At the time Defendant began marketing each of its Pelvic Mesh Products, Defendant was aware that its Pelvic Mesh Products were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011 Safety Communication.

28. The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011 was known or knowable to Defendant and was not disclosed in oral or written communications, direct to consumer advertising in the form of patient brochures, instructions of use or labeling.

29. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS") also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

> *There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh . . . Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.*

The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

30. Defendant knew or should have known about the Products' risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

31. Defendant knew or should have known that its pelvic mesh products, the Monarc Sling inclusive, unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

32. The scientific evidence shows that the material from which Defendant's Products are made (the Monarc Sling included) is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Product, including the Plaintiff.

33. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by the Plaintiff.

34. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." The Monarc Sling was unreasonably susceptible to degradation and fragmentation inside the body.

35. The Monarc Sling was unreasonably susceptible to shrinkage and contraction inside the body.

36. The Monarc Sling was unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

37. The Monarc Sling has been and continues to be marketed to the medical community and to patients as safe, effective, and reliable medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective when compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

38. Defendant omitted the risks, dangers, defects, and disadvantages of the Monarc Sling, and advertised, promoted, marketed, sold and distributed the Monarc Sling as safe medical devices when Defendant knew or should have known that the Monarc Sling was not safe for their intended purposes, and that the Monarc Sling would cause, and did cause, serious medical problems, and in some patients, including Mrs. COMPTON, catastrophic injuries.

39. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, the Monarc Sling has a high rate of failure, injury, and complications, fails to perform as intended, requires frequent and often debilitating re-operations, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making it defective under the law.

40. The specific nature of the Monarc Sling defects include, but are not limited to, the following:

a. the use of polypropylene and collagen material in the Monarc Sling and the immune reactions that result from such material, causing adverse reactions and injuries;

b. the Monarc Sling is designed to be inserted transvaginally, into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Monarc Sling, including, but not limited to, the propensity of the Monarc Sling to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Monarc Sling, which, when placed in women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

e. the propensity of the Monarc Sling for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Monarc Sling, causing it to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where it is implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking); and

g. the propensity of the Monarc Sling for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. the propensity of the collagen Monarc Sling to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. the adverse tissue reactions caused by the collagen Monarc Sling, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. the harshness of animal collagen upon the female pelvic tissue, and the hardening of the product in the body;

l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions;

m. the surgical technique, which is part of Defendant's Monarc Sling, requires the physician to insert the device "blindly" resulting in nerve damage and damage to other internal organs;

n. the design of trocars, devices which are part of Defendant's Monarc Sling and which are used to insert the Monarc into the vagina, are defective because the device requires tissue penetration in nerve rich environments which results frequently in the destruction of nerve endings causing pain and other injuries.

o. The clear coloring of the Monarc sling makes it highly difficult to determine if all of the Monarc sling has been removed during surgery.

41. The Monarc Sling is also defective due to Defendant's failure to adequately warn or instruct the Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. the Monarc Sling' propensities to contract, retract, and/or shrink inside the body;

b. the Monarc Sling's propensities for degradation, fragmentation and/or creep;

c. the Monarc Sling's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Monarc Sling;

f. the risk of chronic infections resulting from the Monarc Sling;

g. the risk of permanent vaginal or pelvic scarring as a result of the Monarc Sling;

h. the risk of permanent vaginal shortening resulting from the Monarc Sling;

i. the risk of recurrent, intractable pelvic pain and other pain resulting from the Monarc Sling;

j. the need for corrective or revision surgery to adjust or remove the Monarc Sling;

k. the severity of complications that could arise as a result of implantation of the Monarc Sling;

l. the hazards associated with the Monarc Sling;

m. the Monarc Sling' defects described herein;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Monarc Sling is no more effective than feasible available alternatives;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Monarc Sling exposes patients to greater risk than feasible available alternatives;

p. treatment of pelvic organ prolapse and stress urinary incontinence with the Monarc Sling makes future surgical repair more difficult than feasible available alternatives;

q. use of the Monarc Sling puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

r. removal of the Monarc Sling due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

s. complete removal of the Monarc Sling may not be possible and may not result in complete resolution of the complications, including pain.

42. Defendant has underreported information about the propensity of the Monarc Sling to fail and cause injury and complications and have made unfounded representations regarding the efficacy and safety of the Monarc Sling through various means and media. Defendant has also underreported information about the injuries caused by the use of the implantation kits and surgical technique instructions that accompany their pelvic meshes.

43. Defendant failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Monarc Sling.

44. Defendant failed to design and establish a safe, effective procedure for removal of the Monarc Sling, or to determine if a safe, effective procedure for removal of the Monarc Sling exists.

45. Feasible and suitable alternatives to the Monarc Sling have existed at all times relevant that do not present the same frequency or severity of risks as do the Monarc Sling.

46. The Monarc Sling was at all times utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use, created the procedures for implanting the devices, provided the surgical kits for implantation, and provided training for the implanting physician.

47. Defendant provided incomplete and insufficient training and information to physicians regarding the use of the Monarc Sling and the aftercare of patients implanted with the Monarc Sling.

48. The specific Monarc Sling implanted in the Plaintiff was in the same or substantially similar condition as they were when they left Defendant's possession, and in the condition directed by and expected by Defendant.

49. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Products include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain and other debilitating complications.

50. In many cases, including Mrs. COMPTON, the women have been forced to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

51. The medical and scientific literature studying the effects of Defendant's pelvic mesh products, like that of the Monarc Sling implanted in Mrs. COMPTON has examined each

of these injuries, conditions, and complications, and has reported that they are causally related to the Products.

52. Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

53. At all relevant times herein, Defendant continued to promote the Monarc Sling as safe and effective even when no clinical trials had been done supporting long or short-term efficacy.

54. In doing so, Defendant failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Product.

55. At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put the Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Products, the Monarc Sling inclusive.

56. The Monarc Sling as designed, manufactured, distributed, sold and/or supplied by Defendant was defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendant's knowledge of lack of safety.

57. As a result of having the Monarc Sling implanted in her, Mrs. COMPTON has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

THIRD CAUSE OF ACTION
NEGLIGENCE

58. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

59. Defendant had a duty to individuals, including the Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Monarc Sling.

60. Defendant was negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Monarc Sling. Defendant breached its aforementioned duty by:

a. Failing to design the Monarc Sling so as to avoid an unreasonable risk of harm to women in whom the Monarc Sling was implanted, including the Plaintiff;

b. Failing to manufacture the Monarc Sling so as to avoid an unreasonable risk of harm to women in whom the Monarc Sling was implanted, including the Plaintiff;

c. Failing to use reasonable care in the testing of the Monarc Sling so as to avoid an unreasonable risk of harm to women in whom the Monarc Sling was implanted, including the Plaintiff;

d. Failing to use reasonable care in inspecting the Monarc Sling so as to avoid an unreasonable risk of harm to women in whom the Monarc Sling was implanted, including the Plaintiff;

e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Monarc Sling.

61. The reasons that Defendant's negligence caused the Monarc Sling to be unreasonably dangerous and defective include, but are not limited to:

a. the use of polypropylene material and/or collagen material in the Monarc Sling and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the Monarc Sling is designed to be inserted transvaginal, into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Monarc Sling, including, but not limited to, the propensity of the Monarc Sling to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Monarc Sling, which, when placed in women, is likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the Monarc Sling for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Monarc Sling, causing it to be improperly mated to the delicate and sensitive areas of the pelvis where it is implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation); and

g. the propensity of the Monarc Sling for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. the propensity of the collagen Monarc Sling to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. the adverse tissue reactions caused by the collagen Monarc Sling, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. the harshness of animal collagen upon the female pelvic tissue, and the hardening of the product in the body;

l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

62. Defendant also negligently failed to warn or instruct the Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. the Monarc Sling's propensities to contract, retract, and/or shrink inside the body;

b. the Monarc Sling's propensities for degradation, fragmentation and/or creep;

c. the Monarc Sling's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Monarc Sling;

f. the risk of chronic infections resulting from the Monarc Sling;

g. the risk of permanent vaginal or pelvic scarring as a result of the Monarc Sling;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Monarc Sling;

i. the need for corrective or revision surgery to adjust or remove the Monarc Sling, as occurred with the Plaintiff herein;

j. the severity of complications that could arise as a result of implantation of the Monarc Sling;

k. the hazards associated with the Monarc Sling;

l. the Monarc Sling's defects described herein;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Monarc Sling is no more effective than feasible available alternatives;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Monarc Sling exposes patients to greater risk than feasible available alternatives;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Monarc Sling makes future surgical repair more difficult than feasible available alternatives;

p. use of the Monarc Sling puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Monarc Sling due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Monarc Sling may not be possible and may not result in complete resolution of the complications, including pain.

63. As a direct and proximate result of Defendant's negligence, Mrs. COMPTON has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendant, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

FOURTH CAUSE OF ACTION
PRODUCT LIABILITY: DESIGN DEFECT

73. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

74. The Monarc Sling implanted in the Plaintiff was not reasonably safe for its intended uses and was defective as described herein with respect to its design. As previously stated, the Monarc Sling's design defects include, but are not limited to:

a. the use of polypropylene material and/or collagen material in the Monarc Sling and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the Monarc Sling is designed to be inserted transvaginally, into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Monarc Sling, including, but not limited to, the propensity of the Monarc Sling to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Monarc Sling, which, when placed in women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the Monarc Sling for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Monarc Sling, causing it to be improperly mated to the delicate and sensitive areas of the pelvis where it is implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation); and

g. the propensity of the Monarc Sling for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. the propensity of the collagen Monarc Sling to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. the adverse tissue reactions caused by the collagen Monarc Sling, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. the harshness of animal collagen upon the female pelvic tissue, and the hardening of the product in the body;

l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions;

m. the clear coloring of the Monarc sling product makes it impossible to determine if the product has been removed in full if and when a revision surgery is necessary.

75. As a direct and proximate result of the Monarc Sling's aforementioned defects as described herein, Mrs. COMPTON has experienced significant mental and physical pain and

suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

76. Defendant is strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

77. As a direct and proximate result of one or more of the above-stated negligent acts, Plaintiff DEBRA COMPTON has suffered and will continue to suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

FIFTH CAUSE OF ACTION
PRODUCT LIABILITY: MANUFACUTRING DEFECT

78. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

79. The Monarc Sling implanted in the Plaintiff was not reasonably safe for its intended uses and was defective as described herein as a matter of law with respect to its manufacture, in that it deviated materially from Defendant's design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to the Plaintiff.

80. As a direct and proximate result of the Monarc Sling' aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and/or corrective

surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

81. Defendant is strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

82. By reason of the foregoing, Plaintiff has suffered injuries and damages as alleged herein.

SIXTH CAUSE OF ACTION
PRODUCT LIABILITY: FAILURE TO WARN

83. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

84. The Monarc Sling implanted in the Plaintiff was not reasonably safe for its intended uses and was defective as described herein as a matter of law due to its lack of appropriate and necessary warnings. Specifically, Defendant did not provide sufficient or adequate warnings regarding, among other subjects:

a. the Monarc Sling's propensities to contract, retract, and/or shrink inside the body;

b. the Monarc Sling's propensities for degradation, fragmentation, disintegration and/or creep;

c. the Monarc Sling' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Monarc Sling;

f. the risk of chronic infections resulting from the Monarc Sling;

g. the risk of permanent vaginal or pelvic scarring as a result of the Monarc Sling;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Monarc Sling;

i. the need for corrective or revision surgery to adjust or remove the Monarc Sling;

j. the severity of complications that could arise as a result of implantation of the Monarc Sling;

k. the hazards associated with the Monarc Sling;

l. treatment of pelvic organ prolapse and stress urinary incontinence with the Monarc Sling is no more effective than feasible available alternatives;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Monarc Sling exposes patients to greater risk than feasible available alternatives;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Monarc Sling makes future surgical repair more difficult than feasible available alternatives;

o. use of the Monarc Sling puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

p. removal of the Monarc Sling due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

q. complete removal of the Monarc Sling may not be possible and may not result in complete resolution of the complications, including pain.

85. As a direct and proximate result of the Monarc Sling's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

86. Defendant is strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging, and selling a defective product.

87. WHEREFORE, Plaintiff demands judgment against Defendant, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

SEVENTH CAUSE OF ACTION
EXPRESS WARRANTY

88. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

89. Defendant made assurances as described herein to the general public, hospitals and health care professionals that the Monarc Sling was safe and reasonably fit for its intended purposes.

90. The Plaintiff and/or her healthcare provider chose the Monarc Sling based upon Defendant's warranties and representations as described herein regarding the safety and fitness of the Monarc Sling.

91. The Plaintiff, individually and/or by and through her physician, reasonably relied upon Defendant's express warranties and guarantees that the Monarc Sling was safe, merchantable, and reasonably fit for its intended purposes.

92. Specifically, the indications for use warrant that "the MONARC Sling System is intended for the placement of a pubourethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency."

93. Defendant breached these express warranties because the Monarc Sling implanted in the Plaintiff was unreasonably dangerous and defective as described herein and not as Defendant had represented in that it did not treat Plaintiff's urinary incontinence, and she continues to suffer from SUI to this day.

94. Defendant's breach of its express warranties resulted in the implantation of an unreasonably dangerous and defective product in the body of the Plaintiff, placing Plaintiff's health and safety in jeopardy.

95. As a direct and proximate result of Defendant's breach of the aforementioned express warranties, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

96. WHEREFORE, Plaintiff demands judgment against Defendant, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

EIGHTH CAUSE OF ACTION
IMPLIED WARRANTY

97. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

98. Defendant impliedly warranted that the Monarc Sling was merchantable and was fit for the ordinary purposes for which it was intended.

99. When the Monarc Sling was implanted in the Plaintiff to treat her pelvic organ prolapse and/or stress urinary incontinence, the Monarc Sling was being used for the ordinary purposes for which it was intended.

100. The Plaintiff, individually and/or by and through her physician, relied upon Defendant's implied warranties of merchantability in consenting to have the Monarc Sling implanted in her.

101. Defendant breached these implied warranties of merchantability because the Product implanted in the Plaintiff was neither merchantable nor suited for its intended uses as warranted.

102. Defendant's breach of their implied warranties resulted in the implantation of unreasonably dangerous and defective Monarc Sling in the body of the Plaintiff, placing Plaintiff's health and safety in jeopardy.

103. As a direct and proximate result of Defendant's breach of the aforementioned implied warranties, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

NINTH CAUSE OF ACTION
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

104. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

105. Defendant carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendant's Monarc Sling to Plaintiff, carelessly and negligently concealing the harmful effects of the Defendant's Monarc Sling from Plaintiff, and carelessly and negligently misrepresented the quality, safety and efficacy of the Monarc Sling.

106. Plaintiff was directly impacted by Defendant's carelessness and negligence, in that Plaintiff has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of being implanted with the Monarc Sling sold and distributed by Defendant and/or because of the nature of their relationship to the individual implanted with the Monarc Sling.

107. As a direct and proximate result of the Defendant's conduct, Plaintiff has been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendant, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

WHEREFORE, Plaintiff demands judgment against Defendant, and requests restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

WHEREFORE, Plaintiff demands judgment against Defendant for such sums, including, but not limited to prejudgment and post-judgment interest, as would be necessary to compensate the Plaintiff for the injuries Plaintiff has and will suffer. Plaintiff further demands judgment against the Defendant for punitive damages. Plaintiff further demands payment the Defendant of the costs and attorney fees of this action and states that the amount of damages sought herein exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction.

Plaintiff further demands payment by Defendant of interest on the above and such other relief as the Court deems just.

December 1, 2022

Respectfully submitted,

/s/ David deBruin

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